December 16, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 94P-0036; *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims; Reopening of the Comment Period
67 Federal Register 69171(November 15, 2002)

Dear Sir/Madam:

These comments are submitted on behalf of the members of the American Bakers Association (ABA), the national trade association representing the wholesale baking industry. ABA membership consists of bakers and bakery suppliers who together are responsible for the manufacture of approximately 80 percent of the baked goods sold in the United States. The purpose of these comments is to voice our strong opposition to the recently proposed cautionary footnote that would be required to accompany foods with *trans* fatty acid declarations, "Intakes of *trans* should be as low as possible" and to provide detailed information to the agency substantiating our concerns.

ABA Strongly Opposes the *Trans* Fatty Acid Cautionary Footnote

While ABA welcomes the opportunity to provide input on the critical food labeling issues concerning *trans* fatty acids ("*trans* fat"), we are very concerned that the approach FDA has proposed through the proposed mandatory footnote statement in nutrition labeling urging consumers to consume as little *trans* fat as possible is unfounded and would mislead consumers and could promote increased consumption of saturated fats in an effort to avoid more healthful food choices containing *trans* fat. The proposed statement is unsubstantiated by competent and reliable scientific evidence in the context in which it would be presented, and would skew consumer food choices in ways presenting a genuine health risk. Additionally, FDA's cautionary footnote proposal fails to satisfy First Amendment requirements applicable to compelled commercial speech and thus cannot be implemented in conformance with law. Further, the cautionary footnote is actually a disincentive to food manufacturers to reformulate products to lower *trans* levels given that the footnote would still be required if there were any measurable amount

of *trans* within the reformulated product (i.e., a reformulated product with a 50% *trans* decrease from 4 grams to 2 grams per serving). For these reasons, ABA strongly opposes FDA's proposed mandatory footnote statement and urges FDA to eliminate this requirement from the final rule on *trans* fat labeling.

FDA's Proposed Cautionary Footnote is Unsubstantiated and Inconsistent with IOM/NAS Macronutrient Report

FDA is proposing to require an asterisk (or other symbol) in the % DV column for *trans* fat when it is listed that is tied to a similar symbol at the bottom of the Nutrition Facts Box that is followed by the statement "Intake of *trans* fat should be as low as possible." ABA understands that FDA intends this footnote requirement to "provide guidance to consumers when using the quantitative information to help maintain healthy dietary practices." This guidance is taken from the Institute of Medicine/National Academy of Sciences (IOM/NAS) macronutrient report, however, there is significant controversy concerning whether the IOM/NAS report itself substantiates the proposed cautionary footnote statement (i.e., the complete IOM/NAS statement provides: "*trans* fat consumption be as low as possible while consuming a nutritionally adequate diet"), and whether such a statement would be deceptive considering the overall weight of the scientific evidence concerning *trans* fat including the emerging scientific evidence supporting the health benefits of conjugated linoleic acid (CLA)-*trans* fat. ABA is also very concerned that the IOM/NAS study did not receive adequate peer-review given the significant weight it is given in this latest FDA proposal.

The Cautionary Footnote Promotes Consumer Confusion in Making Sound Nutrition Choices

Even if a peer review of the NAS report were found to support the scientific accuracy of the statement the FDA footnote proposal relies on, this would not be sufficient information to justify requiring that this statement be required in food labeling. Consumers rely on food labeling to assist them in making choices between real food product alternatives presented to them in the marketplace. Food products that are formulated to contain *trans* fat commonly are more healthful alternatives to food products formulated with saturated fats. The specific language, "as low as possible", is vague and seems open to a variety of potential interpretations by consumers. Given this marketplace context, the proposed cautionary footnote statement - - even if technically correct from a purely scientific context, would none the less function to exaggerate the relative importance of avoiding *trans* fat in the context of the concrete food choices

presented. The proposed footnote statement may readily be interpreted as an unfounded warning statement to consumers that foods containing *trans* fat should be avoided at all costs. This take-away message is false and misleading, and does not square with the anti-deception standards FDA would apply to voluntary label statements manufacturers may choose to make in food labeling. In addition, there is no consumer testing or other evidence in the record establishing that the cautionary footnote statement functions to alleviate any genuine harm to consumers. As discussed further below, under the First Amendment, FDA lacks authority to impose compelled commercial speech requirements of this kind except where it first establishes that the specific requirement is effective in remedying a genuine harm that would persist in the absence of the requirement. FDA has provided no evidence that can satisfy this First Amendment standard.

Additionally, there is no evidence that the proposed statement has been evaluated with respect to consumer behavior, to evaluate whether the statement is likely to trigger irrational, exaggerated fears of *trans* fat that would foster avoidance behaviors and unhealthy distortions in dietary intake. Conducting such an evaluation before instituting a compelled speech requirement of this kind would support FDA responsibilities under the First Amendment, and appears necessary to ensure that the public health objectives articulated by FDA are, in fact, promoted by mandatory labeling.

Notably, because of the widespread presence of *trans* fat in the food supply, the FDA notice expresses specific concern that defining concrete limits on *trans* fat intake at this time would "require extraordinary changes in dietary intake patterns that might introduce other undesirable effects and unknown health risks . . . ." The FDA notice provides no evidence that the proposed mandatory labeling, which implies that a zero tolerance level is best, will promote healthy dietary intake patterns, rather than adverse distortions in dietary intake patterns, including perception with respect to bread and other grain based products that may occur.

In the 1999 proposal, FDA stated that, because the average intake of saturated fat exceeds that of *trans* fat by five fold, it is important that *trans* fat labeling not divert consumer attention away from risks associated with saturated fat and dietary modifications aimed to reduce overall cardiovascular disease risk. It appears that the proposed cautionary footnote would indeed sidetrack consumers when they are making dietary choices regarding foods that include saturated and *trans* fats.

ABA notes that there is no evidence that the proposed cautionary footnote will enhance consumer understanding of the Nutrition Facts information, especially in the absence of agency supported nutrition education on this issue. Information of several types and formats (quantitative declarations, Daily Values (DV's), footnotes, etc.) is already required, and the cautionary footnote statement expands the diversity of forms in use. The original rationale for the standardized Nutrition Facts panel was based on the concept that a simple, uncluttered presentation of nutrition information was necessary to ensure that consumers would observe and comprehend the information. (See 58 Fed. Reg. (January 6, 1993).) The proposed cautionary footnote appears inconsistent with this rationale, and ABA strongly believes would cause consumer confusion.

The proposed cautionary footnote would lead to substitution of saturated fat for *trans* fat in both food product formulation by industry and in dietary patterns of consumers. Inevitably, the proposed rule would lead to a return to more consumption of saturated fat and would undermine the nutritional message regarding saturated fat that FDA has worked diligently to convey to consumers. In effect, consumers would be encouraged to substitute saturated for *trans* fat in their daily diets. For example, a manufacturer wishing to avoid the proposed footnote might choose lard (6 g of saturated fat, 12 milligrams (mg) of cholesterol and 0 g of *trans* fat) over solid phase vegetable shortening (3.5 g of saturated fat, 2.5 g of *trans* fat, and no cholesterol). A consumer persuaded by the proposed footnote to avoid *trans* fat might choose butter (7 g of saturated fat, 31 mg of cholesterol, 0 g of *trans* fat) over vegetable oil spread (2 g of saturated fat, 2 g of *trans* fat, no cholesterol).

FDA's Authority to Implement the Footnote in Conformance with First Amendment Standards Has Not Been Established

ABA is concerned that FDA's proposed cautionary footnote statement is in effect a warning statement and is inconsistent with governing First Amendment precedents**.** Under the First Amendment, the government's authority to restrict the freedom of expression through the regulation of commercial speech is sharply limited. Before instituting controls on the content of commercial speech, the government first must establish that the specific restriction satisfies the requirements of the "Central Hudson" test (See *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n. of New York*, 447 U.S. 557 (1980).) Under this test, regulatory controls on the content of commercial speech cannot be instituted except where they are established to be effective in mitigating a genuine harm to the public. The Supreme Court has emphasized that the government's burden of proof in this regard cannot be satisfied by mere speculation or conjecture.

Rather, there must be real evidence to "demonstrate that the harms [the government] recites are real" and the specific restriction "will alleviate them to a material degree." (*Edenfield v. Fane* U.S. 761,770-71 (1993).)

More particularly, regulatory agencies must establish that the speech restriction that would be established by regulation serves a substantial government interest in alleviating a genuine public harm; the restriction directly advances that interest and is carefully tailored so that the specific retriction imposed on the content of commercial expression is not broader that necessary to alleviate the public harm the regulation is intended to remedy. This standard applies to regulations that restrict the freedom of expression not only by banning speech, but also by compelling speech, as the proposed *trans* fat footnote would do. (*International Dairy Foods Association v. Amestoy*, 92 F.3d 67, 73 (2d Cir. 1996). (Ruling that mandatory labeling operating as "the functional equivalent of a warning" failed to satisfy First Amendment standards.)

FDA's proposed cautionary *trans* footnote clearly fails to satisfy the requirements of the *Central Hudson* test, and thus cannot be implemented consistent with the boundaries the First Amendment places on the agency's legal authority.

ABA Opposes De facto Daily Value (DV) for *Trans* of Zero

To most consumers, the recommendation that consumption of a nutrient "should be as low as possible" means that they should avoid it; ideally their intake should be zero. Although FDA states it is not proposing to establish a Daily Value for *trans* fat, the proposed footnote would effectively establish a Daily Value of zero. The problem with the agency's approach is that it communicates a misleading message about the relative significance of *trans* fat and saturated fat in the daily diet. FDA is effectively proposing to retain the Daily Value of 20 grams (g) for saturated fat while setting a Daily Value of 0 g for *trans* fat. This message implies that a healthy diet may include up to 20 grams of saturated fat per day, but no *trans* fat. Thus the proposed cautionary footnote, read in conjunction with other aspects of the existing nutrition label, would promote a misleading message about the relative significance of *trans* fat and saturated fat in the daily diet.

Pending New Dietary Reference Intake (DRI) Recommendations Need to be Considered

ABA believes it is premature to change the Nutrition Facts for *trans* fat before FDA has reviewed the recommendations and data for DRIs. Outside the footnote, if the nutrition label is to be revised to reflect the DRI recommendations for *trans* fat, as is expected, this action should be done systematically. FDA should wait until the DRI

recommendations have been issued before incorporating changes to nutrition labeling regulations. From a regulatory standpoint it would be more logical, helpful to consumer understanding and cost effective to have one succinct set of changes for *trans* fat labeling. If the changes occur incrementally rather than at once, industry will have to bear the burden of piecemeal changes that will cost million of dollars.

New Cost Impact Analysis Needed

FDA' preliminary economic impact analysis from the original 1999 *trans* fat labeling proposal grossly understated the cost to industry to make nutrition labeling changes for *trans* fat. Given the broad expansion of products that could be encompassed under the new and the more complex proposal, ABA believes strongly that a new cost impact analysis is necessary.

Additionally, ABA references the review of FDA's original 1999 cost analysis for the *trans* labeling proposal in a report from The Regulatory Studies Program (RSP) of the Mercatus Center at George Mason University which questions FDA's interpretation of issues regarding consumer response to proposed labeling changes and expected benefits. The full paper can be found at www.mercatus.org/research/RSP20020.html . (As part of RSP's mission, it produces thoughtful, independent analyses of agency rulemaking proposals from the public interest perspective.)

ABA believes that virtually all bakery products would have to change their package labeling if the new proposal proceeds. In some cases, given the fact that labeling space is already greatly limited on bakery packages, the addition of two additional labeling lines could necessitate a total redesign of a package, thus doubling the cost for changes (i.e., plate changes, nutrition facts changes and package redesign). Labeling changes could be required for all products to add a separate line declaring the grams of *trans* fat per serving to the nutrition facts panel, even if zero, as well as the *trans* fat Daily value footnote or "not a significant source of…" statement. ABA believes the cost for these extensive labeling changes for the baking industry alone would be upwards of tens of millions of dollars.

Scope & Format of the Mandatory Nutrition Labeling Requirement

ABA thinks that it would be appropriate for *trans* fat declaration to be triggered under the same circumstances comparable to those applicable to monounsaturated and polyunsaturated fat (e.g., when fatty acid claims/information is provided in labeling). Additionally, FDA should only require declaration of the amount of *trans* fat in Nutrition Facts – without the warning statement footnote below the Facts panel. FDA is

proposing that *trans* fat be declared using the same format that applies to polyunsaturated and monounsaturated fat. Under section 101.9(c)(2)(ii)-(iii) of FDA regulations, these fatty acids must appear indented below "total fat," and expressed as grams per serving, declaring either "polyunsaturated" or "monounsaturated" fat on a voluntary basis triggers the requirement that both classes of fatty acids be declared on a mandatory basis. These must also be declared whenever claims are made about fatty acids or cholesterol. The declaration must be rounded to the nearest 0.5 gram increment below 5 grams and to the nearest gram increment above 5 grams.

A significant change that ABA recommends apart from the FDA proposal is how products with less than 0.5 grams of *trans* per serving be labeled. ABA strongly recommends that food products that contain less than 0.5 grams of *trans* per serving should not need labeling since the level would be considered insignificant and in effect zero. This rational and cost effective approach would disclose to consumers all of the material information they need to make informed dietary choices. Additionally, it would dramatically cut the number of packages that would need to be reformatted only to state "zero".

Contradictory Definitions for "*Trans* Fat"

In FDA's 1999 proposed rule, the agency defined *trans* fat as "unsaturated fatty acids that contain one or more isolated (*i.e.*, non-conjugated) double bonds in a *trans* configuration." 64 Fed. Reg. 62746, 62795 (Nov. 17, 1999). The IOM/NAS report defines *trans* fat as "unsaturated *fatty* acids that contain at least one double bond in the *trans* configuration." The variation of these two definitions could prove problematic with regards to food labeling. For example, conjugated linoleic acid (CLA) is included in the IOM/NAS definition of "*trans* fatty acids," but not in the FDA definition. CLA has been found to have positive health attributes (*e.g.*, anti-carcinogenicity, anti-atherogenicity, enhanced immune response, anti-diabetic properties). However, because it is considered a *trans* fatty acid under the IOM/NAS definition, the proposed cautionary footnote would advise consumers to avoid it, and manufacturers would be encouraged to remove it from their products.

Additionally, it is unclear from the recent notice what the specific trigger for mandatory labeling would be. ABA notes that under the Administrative Procedures Act significant regulatory changes require that adequate notice be given to the public so that they can comment. If the trigger is different than in the Agency's original 1999 proposal, then additional time for public comment would certainly be justified.

ABA's previous comments (April 14, 2000) supported FDA's proposed definition of "*trans* fat" to include "unsaturated fatty acids containing one or more isolated (i.e., nonconjugated) double bonds and to exclude *trans* fats with conjugated double bonds."

Nutrient Content and Health Claims

In the present proceedings, FDA has indicated that the Agency intends to move forward with a final rule concerning the mandatory declaration of *trans* fat in food labeling, while taking no further action on the remainder of the issues covered by the original proposal at this time. FDA originally proposed to amend regulations governing nutrient content and health claims to integrate *trans* fat limits into existing saturated fat limits and to establish requirements defining "*trans* fat free" claims.

Originally, FDA proposed to treat *trans* fat and saturated fat virtually the same for nutrition labeling purposes, and for purposes of defining fatty acid limits for nutrition content and health claims. In its April 14, 2000 comments, ABA challenged the premise of the FDA proposal and set forth a detailed explanation of product formulation which showed that the FDA proposal was unfounded, and would operate to encourage increased consumption of saturated fat to the detriment of public health. The FDA proposal in this regard suffered from ivory tower deliberations concerning principles of human metabolism, but failed to consider the real world food science principles of ingredient composition, and the substitution of *trans* fat containing ingredients for saturated fat containing ingredients in actual product formulations. The extent to which saturated fat and *trans* fat produce comparable biological effects on a gram-for-gram basis remains a matter of substantial controversy. Regardless of how this nutritional science debate evolves, any treatment of saturated fat and *trans* fat as the same for food labeling purposes cannot be justified in view of the chemical differences and formulation principles ABA comments have discussed.

ABA notes that the current proposal treats saturated fat and *trans* fat separately for purposes of nutritional labeling. In the case that FDA proceeds with further policy development concerning *trans* fat criteria defining nutrient content and health claims, ABA believes that *trans* fat and saturated fat limits must be kept separate. The First Amendment standards that would define the limits of FDA authority, could not be satisfied for food labeling regulations that would treat *trans* fat and saturated fat the same way in view of the scientific issues presented, and ABA would continue to oppose policy developments that fail to satisfy these standards.

ABA appreciates this opportunity to comment on FDA's reopening of the *trans* fatty acid nutrition labeling proposal. The Association is hopeful that the detailed concerns outlined above regarding the cautionary footnote, as well as our additional comments on other issues relating to *trans* fat labeling that impact the wholesale baking

industry, will be useful to FDA as the Agency moves forward to finalize policy on this issue. The technical contact for these comments is Lee Sanders, ABA Vice President, Regulatory and Technical Services, American Bakers Association, 1350 I Street, N.W., Suite 1290 Washington, D.C. 20005-3305 (telephone) 202-789-0300, (fax) 202-898-1164.

Respectfully submitted,

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